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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,649	08/01/2000	DANIEL LADANT	03495.0190	8848

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
1645	22

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/555,649

Applicant(s)

LADANT ET AL.

Examiner

Robert A. Zeman

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached.

3. ☐ Applicant's reply has overcome the following rejection(s): see attached.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 10-15, 17-22, 25-32, 34-38 and 46-62.

Claim(s) withdrawn from consideration: 1-9, 23, 24 and 39-45.

8. ☒ The proposed drawing correction filed on 11 August 2003 is a) ☒ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

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ADVISORY ACTION

Drawings

The drawings were received on 8-11-2003. These drawings are acceptable and have been forwarded to the Draftsman.

Applicant's request for reconsideration of the finality of the rejection of the last Office action has been fully considered and deemed non-persuasive and, therefore, the finality of that action is maintained.

The amendment after final rejection filed on 8-11-2003 has not been entered. The proposed amendment raises new issues that would require further consideration and/or search. Minimally, claims 15, 46, 51, 52 raise new issues under 35 U.S.C. 112, second paragraph.

Consequently, claims 1-15, 17-32 and 34-62 are pending. Claims 1-9, 23-24 and 39-34 remain withdrawn from consideration. Claims 10-15, 17-22, 25-32 34-38 and 46-62 are currently under examination.

Claim Rejections Withdrawn

Based on further consideration by the examiner, the rejection of claims 10 and 25 under 35 U.S.C. 112, second paragraph as being rendered vague and indefinite by the use of the phrase "amplifying a signal generated by..." is withdrawn.

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Based on further consideration by the examiner, the rejection of claim 17 under 25 U.S.C. 112, second paragraph as being rendered vague and indefinite by the use of the phrase "detected by signal amplification" is withdrawn.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-15, 17-22, 25-32, 34-38 and 46-62 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fields et al. (U.S. Patent 5,468,614) essentially for the reasons set forth in the rejection of claims 10-17, 20-22, 25-33 and 36-38 in the previous Office action.

Applicant argues:

1. Fields et al. does not recite the use (or provide motivation for the use) of either adenylate cyclase or guanylate cyclase (specifically) or any enzyme (generally).

Applicant's arguments have been fully considered and deemed non-persuasive since they are predicated, in part, on a non-entered amendment.

The instant claims are drawn to methods of selecting a molecule of interest that can bind to a target ligand (or identifying a substance that modulates said binding) utilizing signal amplification system comprising a bacterial multi-hybrid system utilizing enzyme fragments and/or enzyme modulators to detect protein-protein interactions. The instant claims are also drawn to methods wherein said selection is done in a bacterium.

With regard to Applicant's assertion that Fields et al. does not recite (or provide motivation for) the use of any enzyme, a close reading of Fields et al. (column 7, line 50 to column 8, line 22) discloses a method that can be applied to "any detectable function requiring separable domains of an amino acid sequence which can be reconstituted. Said method detects the interaction between a first test protein and a second test protein. The detectable function is provided by an amino acid sequence which includes a first domain and a second domain which are capable of producing a detectable function (enzyme activity for example) when they are in sufficient proximity to each other in the host cell (see column 7, lines 50-61). As pointed out by Applicant in his response,

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Fields et al disclose, "the method of the present invention can be applied more generally to any detectable function requiring separable domains of an amino acid sequence which can be reconstituted".

This would include enzyme activity. Moreover, it should be noted that the specific embodiments with regard to the specific components utilized in the hybrid system disclosed by Fields et al. constitute obvious variants of the disclosed system.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-15, 17-22, 25-32, 34-38 and 46-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-23 and 24-38 of copending Application No. 09/973013. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of selecting a molecule of interest that can bind to a target ligand (or identifying a substance that modulates said binding) utilizing signal amplification system comprising a bacterial multi-hybrid system utilizing enzyme fragments and/or enzyme modulators to detect

protein-protein interactions. The instant claims are also drawn to methods wherein said selection is done in a bacterium.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant argues:

1. No patent has been issued from application No. 09/917,013 and so there is no extension of the right to exclude.

Applicant's arguments have been fully considered and deemed non-persuasive. As an initial note, the rejection was made over U.S. Application 09/973,013 not 09/917,013 as asserted by Applicant. Moreover, since the instant application is not in condition for allowance the status of the claims in the copending application cannot be determined and hence the rejection is maintained until the time when the instant application is in condition for allowance at which time said rejection will either be made non-provisional or withdrawn.

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 10-15, 17-22, 25-32, 34-38 and 46-62 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record.

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The rejection of claims 10 and 25 under 25 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "capable of" is maintained for reasons of record.

Applicant's arguments are predicated on a non-entered amendment and hence are deemed non-persuasive.

The rejection of claims 10, 13, 17, 21 and 25-38 under 25 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "interaction" is maintained for reasons of record. Applicant's arguments are predicated on a non-entered amendment and hence are deemed non-persuasive.

The rejection of claims 20 and 36 under 25 U.S.C. 112, second paragraph as being rendered vague and indefinite by the use of the phrase "gene with a selectable phenotype" is maintained for reasons of record. Applicant's arguments are predicated on a non-entered amendment and hence are deemed non-persuasive.

The rejection of claims 22 and 38 under 25 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "performed in a bacterial strain" is maintained for reasons of record. Applicant's arguments are predicated on a non-entered amendment and hence are deemed non-persuasive.

The rejection of claims 46 and 52 under 25 U.S.C. 112, second paragraph, as being rendered vague and indefinite by reciting improper Markush language is maintained for reasons of record. Applicant's arguments are predicated on a non-entered amendment and hence are deemed non-persuasive. It should be noted the proposed amendments still contain improper Markush language. The **penultimate member** of the Markush group should be preceded by the article "or".

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The rejection of claims 49 and 55 under 25 U.S.C. 112, second paragraph, for not having proper antecedent basis for the limitation "color marker" in line 1 is maintained for reasons of record. Applicant's arguments are predicated on a non-entered amendment and hence are deemed non-persuasive.

The rejection of claims 51 and 57 under 25 U.S.C. 112, second paragraph, for not having proper antecedent basis for the limitation "the phage" in line 1 is maintained for reasons of record. It should be noted that Applicant did not address this rejection in his response.

The rejection of claim 59 under 25 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "bacterial cell" is maintained for reasons of record. It should be noted that Applicant did not address this rejection in his response.

The rejection of claim 60 under 25 U.S.C. 112, second paragraph, as being vague and indefinite for being dependent on a canceled claim is maintained for reasons of record. Applicant's arguments are predicated on a non-entered amendment and hence are deemed non-persuasive.

Conclusion

No claim is allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Robert A. Zeman
September 11, 2003